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| 09 759,056 | 01 11 2001 | Diane Pennica | GENENT.2827A2 | 1938 |

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| EXAMINER |
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BORIN, MICHAEL L

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| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 05/20/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/759,056

Applicant(s)

Pennica et al

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-95 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) Notice of References Cited PTO 892 | 4) Interview Summary PTO 413 Paper No. s |
| 2) Notice of Draftsperson's Patent Drawing Review PTO 948 | 5) Notice of Informal Patent Application PTO 152 |
| 3) Information Disclosure Statement with 37 CFR 1.102(a) signature | |

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Part III DETAILED ACTION

Claims 1-95 are currently pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 9-11, 15,16,18-21 drawn to isolated nucleic acids encoding PRO polypeptides, expression vectors and cells comprising the vector, classified in class 536, subclass 23.1 and class 935, subclass 66.
- II. Claims 5-8,15,16,18-21, drawn to isolated nucleic acids having similarity to nucleic acids encoding polypeptides having certain ATCC deposit numbers, expression vectors and cells comprising the vector, classified in class 536, subclass 23.1 and class 935, subclass 66.
- III. Claims 12, 15,16,18-21 drawn to isolated nucleic acids encoding peptides, the latter scoring >80% to peptides of SEQ ID Nos 2 and 5, expression vectors and cells comprising the vector, classified in class 536, subclass 23.1 and class 935, subclass 66.
- IV. Claims 13,14,15,16,18-21 drawn to isolated nucleic acid of >765 nucleotides and produced by hybridization to DNA molecule of Group I, expression vectors and cells comprising the vector, classified in class 536, subclass 23.1 and class 935, subclass 66¹.
- V. Claim 17 drawn to isolated nucleic acids having certain ATCC deposit numbers, classified in class 536, subclass 23.1.
- VI. Claim 22, drawn to method of making of a Stra6 polypeptide, classified in class 435, subclass 91.1

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VII. Claims 23,24,28,52 drawn to polypeptides SEQ ID Nos 2 and 5, fragments and compositions thereof, classified in class 530, subclass 300, in general.

VIII. Claims 25,26 drawn to polypeptides encoded by nucleic acids having certain ATCC deposit numbers, classified in class 530, subclass 300, in general.

IX. Claim 27 drawn to a polypeptide scoring >80% to peptides of SEQ ID Nos 2 or 5, classified in class 530, subclass 300, in general.

X. Claim 27 drawn to a polypeptide obtained by cell culturing (the identity of a polypeptide is not defined), classified in class 530, subclass 388.1.

XI. Claims 31-33, drawn to peptide conjugates, classified in class 424, subclass 178.1.

XII. Claims 34-44, 52, drawn to an antibody to a polypeptide and compositions thereof, classified in class 530, subclass 388.1.

XIII. Claims 45-48, drawn to a nucleic acids encoding an antibody of Group X, expression vectors and cells comprising the vector, classified in class 536, subclass 23.1 and class 935, subclass 66.

XIV. Claim 49, drawn to an agonist to Stra6 polypeptide, and compositions thereof, which will be classifiable only upon selection of an ultimate compound species due to indefiniteness of the term "an agonist".

XV. Claims 50,51, 93-95 drawn to an antagonist to Stra6 polypeptide, and compositions thereof, which will be classifiable only upon selection of an ultimate compound species due to indefiniteness of the term "an antagonist".

XVI. Claims 53,54, drawn to isolated nucleic having >80% similarity to nucleic acids encoding fragments of peptides of SEQ ID Nos 2 or 5, classified in class 536, subclass 23.1.

XVII. Claim 55 drawn to isolated nucleic acids encoding peptides, the latter

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scoring >80% to fragments of peptides of SEQ ID Nos 2 and 5, expression vectors and cells comprising the vector, classified in class 536, subclass 23.1 and class 935, subclass 66.

XVIII. Claims 56, 57 drawn peptides having having >80% similarity to fragments of peptides of SEQ ID Nos 2 or 5, classified in class 530, subclass 300, in general.

XIX. Claim 58, drawn to peptides scoring >80% positives to fragments of peptides of SEQ ID Nos 2 and 5, classified in class 530, subclass 300, in general.

XX. Claims 59-61, drawn to antibody-based method of screening, classified in class 435, subclass 7.1.

XXI. Claim 62 drawn to gene-based method of screening, classified in class 435, subclass 6.

XXII. Claims 63-65, drawn to antibody-based method of diagnostics of tumor, classified in class 424, subclass 130.1.

XXIII. Claims 66,67, drawn to antibody-based method of inhibiting tumor cell growth, classified in class 424, subclass 130.1.

XXIV. Claims 68,75-78, drawn to antisense-based method of inhibiting tumor cell growth, classified in class 536, subclass 24.5.

XXV. Claims 79-81 drawn to an article of manufacture containing anti Stra6 antibody,classified in class 424, subclass 130.1.

XXVI. Claims 79,80,82 drawn to an article of manufacture containing an antisense oligonucleotide,classified in class 536, subclass 24.5.

XXVII. Claims 83-85 drawn to a peptide-based method of screening , classified in class 435, subclass 6.

XXVIII. Claim 86 drawn to gene-based method of screening in the presence of

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a Stra6 peptide, classified in class 435, subclass 6.

XXIX. Claims 87,88, drawn to antibody-based method of identifying expression inhibitors , classified in class, subclass .

XXX. Claims 87,89, drawn to antisense-based method of of identifying expression inhibitors, classified in class, subclass .

XXXI. Claim 90 drawn to an antibody,

XXXII. Claim 91, drawn to a small molecule.

The inventions are distinct, each from the other because of the following reasons:

In general, the nucleic acids, antisense molecules, peptides, peptide conjugates, antibodies, small molecules recited in the claims are drawn to independent and/or patentably distinct compounds since each of these compounds possess different structure (e.g.,primary, secondary and tertiary structure) and/or physico-chemical properties, and/or capable of separate manufacture and/or use. The correspondent methods of use are independent and/or distinct due to the use of different patentably distinct agents (e.g., DNA, peptides, etc) and with different

Inventions of Groups I, XII, XVI, XVII to independent and/or patentably

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distinct nucleic acid compounds since each of these compounds possess different structure, and/or physico-chemical properties, and/or capable of separate manufacture and/or use. Additionally, these different groups do not share a common structure which elicits a common activity, and will have separate enablement requirements. Note, that the inventions may be related as disclosed but patentably distinct as claimed. The inventions would require non-coextensive structure search and a reference teaching one sequence (e.g., of group I) would not teach a sequence of any flanking region (i.e., of Group II or III).

Similarly, Groups VII-XI, XVIII,XIX, and groups XII, XXXI are drawn to structurally different polypeptide and antibody products, respectively. Note, again, that the inventions may be related as disclosed but patentably distinct as claimed.

Inventions of groups XX-XXIV, XXVII-XXX are related as independent methods which are not connected in design, operation or effect because the methods use different agents and/or have different modes of operation, different functions, or different effects, and/or they are not disclosed as capable of use together.

Products of Groups I-XI, XIII-XIX, XXV, XXVI,XXXI, XXXII, and methods of Groups XX-XXIV, XXVII-XXX are related as either a product and process of use of another product or a process of using the product as claimed.

Products of Groups I-XI, XIII-XIX, XXV, XXVI,XXXI, XXXII, and methods of Groups XX-XXIV, XXVII-XXX are related as either a product and process of use of another product or a process of using the product as claimed.

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with another materially different product (e.g., diagnostics of tumor of Group XXII can be carried out with other antibodies or peptides), or the product as claimed can be used in a materially different process of using that product (e.g., the product of Group XII can be used in alternative methods of Groups XX, XXII, XXIII, XXIX), or the product as claimed can be used in a materially different processes (e.g., peptides of Groups XVII, IXI can be used in peptide synthesis.

Sequence Election Requirement Applicable to All Groups

In addition, a further restriction requirement is applied to each Group which recite distinct sequences of nucleic acids and/or proteins. Each sequence is patentably distinct because they are unrelated sequences. **For an elected Group drawn to amino acid or nucleotide sequences, the Applicants must further elect a single sequence.** Examination of such Group will be limited only to one elected sequence.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and the necessity for non-coextensive literature searches restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature, related to the status of the application or to the examiner's office, should be directed to the receptionist, whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D.
PRIMARY EXAMINER